

Application No.: 09/960132

Case No.: 53964US002

Remarks

Favorable reconsideration of this application in the light of the following discussion is respectfully requested. Claims 1-21 are pending in this application for consideration, claims 22 has been withdrawn.

Election/Restriction Requirement Under 35 U.S.C. 121

Restriction to one of the following inventions was required under 35 U.S.C. 121:

1. Claims 1-21, drawn to a method of selectively removing volatile components, classified in class 427, subclass 386.
2. Claim 22, drawn to a method of forming a transdermal drug delivery composition, classified in class 427, subclass 2.31.

The Examiner averred that the inventions are distinct, each from the other because the different inventions are not disclosed as capable of use together and have different modes of operation, function, and effect. According to the Examiner, a method of selectively removing volatile components is distinct and unrelated in operation, function, and effect to a method of making a transdermal drug delivery composition.

The Examiner averred that restriction for examination purposes as indicated is proper because the inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification.

During a telephone conversation with the undersigned attorney on 7/17/2003, a provisional election was made with traverse to prosecute the invention of Group 1, claims 1-21. The Examiner required affirmation of this election by applicants in replying to this Office Action. Claim 22 was withdrawn from further consideration by the Examiner.

Applicants' Response to the Restriction under 35 U.S.C. 121

Applicants affirm the election, with traverse, to prosecute the invention of group I comprising a method of selectively removing volatile components, claims 1-21.

Applicants respectfully traverse the restriction requirement. M.P.E.P. § 803 requires that the two conditions be met for a proper requirement for restriction between patentably distinct

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inventions. First, the inventions must be independent or distinct as claimed. Second, there must also be serious burden on the Examiner if restriction is not required (see M.P.E.P. §803.02; §806.04 (a)-(j); §808.01 (a); and §808.02).

Applicants submit the restriction between groups I and II is improper because the claims would not impose a serious burden on the Examiner if both groups were prosecuted under the same application. In support, applicants respectfully point out that both groups I and II represent related methods in the same class. Reconsideration is respectfully requested.

Rejections under 35 U.S.C. § 103

Claims 1-4 and 6-21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Garbe et al (WO 96/08229) in view of Huelsman et al (5,694,701). According to the Examiner, Garbe et al teaches a method of coating a coating formulation onto a first substrate surface of a substrate, wherein the substrate is an adhesive coated sheet or web material in the form of an article such as a tape, patch, or sheet. The Examiner stated that the coating formulation of Garbe comprises a solvent, drugs, and softeners. While Garbe does not specifically teach that the drugs and softeners are "volatile" and "liquid", the Examiner noted that the drugs and softeners of Garbe are the same as the drugs and "excipients" claimed by Applicant. Therefore according to the Examiner, the drugs and softeners/excipients are inherently volatile liquids, as required by claim 1. After coating, Garbe teaches that the substrate is dried. The Examiner indicated that what Garbe fails to teach is a method of drying.

The Examiner stated that Huelsman teaches a method of drying a coated web substrate, such as an adhesive-coated web or a tape to remove solvent. The Examiner noted that method of Huelsman removed solvent in a controlled fashion, by slowing down the rate of evaporation or stopping the evaporation completely, even in liquid coatings with multiple solvents. The Examiner noted that Huelsman's method involves positioning the coated substrate requiring solvent removal between a condensing surface and a heating surface, with the coated surface facing the condensing surface.

Since Garbe teaches drying an adhesive coated web, sheet, or tape and Huelsman teaches a method of controllably drying an adhesive coated web or a tape to remove solvent therefrom, the Examiner averred that Huelsman would have reasonably suggested his drying mechanism in

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the method of Garbe. The Examiner concluded that it would have been obvious to one of ordinary skill in the art to use the teachings of Huelsman in the method of Garbe to provide Garbe with a controlled method to remove solvent from his adhesive coated web, sheet, or tape. The Examiner averred that because of Garbe's teaching regarding the use of therapeutic drugs in his coating, which are often temperature-sensitive, it would have been obvious to one of ordinary skill in the art to look to the prior art for a method of controllably removing solvents, such as is taught by Huelsman, in a manner which does not damage or remove the expensive therapeutic agents contained therein.

Because Huelsman teaches a method of solvent removal, the Examiner averred that the method of Garbe in view of Huelsman would have inherently selectively removed solvent from the coated substrate, as required by claim 1, and left the drugs and excipients behind, as required by claim 2. Thus, the Examiner stated it would have been obvious to one of ordinary skill in the art to select temperatures such that the drugs and excipients are not damaged or removed during the drying process in order to maintain the integrity and usefulness of the adhesive-coated substrate.

Regarding claims 3 and 4, it is the Examiner's position that selection of heating surface temperatures is within the skill of an ordinary artisan intending to optimize results for evaporating solvent. The Examiner averred that one of ordinary skill would select an appropriate temperature for a given solvent within a given composition.

Regarding claim 6, the Examiner noted that Huelsman teaches that the condensing surface may be 5 cm from the coated web or closer, such as less than 1 cm, thus overlapping the range claimed by Applicant.

The Examiner stated that Huelsman teaches condensing the solvent vapor on the condensing surface, forming a condensate and removing the condensate while it remains in a liquid state for collection, as required by claims 7-8.

Regarding claim 9, the Examiner averred that Garbe teaches the use of ethyl acetate, methanol, acetone, ethanol, isopropanol, or toluene, among others, as solvent.

Regarding claims 10-11, the Examiner stated that Garbe teaches the use of nitroglycerin and scopolamine, as required by claim 11. The Examiner noted that these drugs must inherently be liquid, as required by claim 10, just as they are in applicant's claims because applicant claims

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a "liquid drug", such as "nicotine, nitroglycerin, or scopolamine". Additionally, the drugs of Garbe are supplied in a matrix "substantially free of solid", indicating a liquid form of the drugs.

Regarding claims 12-14, the Examiner suggested that Garbe teaches the use of softeners matching the list of excipients required by claims 13-14.

Regarding claim 15, the Examiner stated that Garbe teaches the use of testosterone as the drug of his formulation.

Regarding claim 16, the Examiner averred that Garbe teaches that the coated web substrate may be a transdermal drug delivery composition.

Regarding claims 17-19, according to the Examiner the transdermal composition of Garbe may include an adhesive, such as an acrylate.

Regarding claims 20-21, the Examiner stated that the substrate of Garbe includes a release liner and backing film.

Claim 5 was objected to by the Examiner as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicants' Response to the Rejections under 35 U.S.C. § 103

Applicants aver that the present invention is patentable over Garbe et al (WO 96/08229) (hereinafter referred to as "Garbe") in view of Huelsman et al (5,694,701) (hereinafter referred to as "Huelsman"). Garbe discloses a matrix for transdermal drug delivery. The transdermal drug delivery device includes a backing and a matrix adhered to one side of the backing. The matrices of Garbe are generally an adhesive coated material applied onto the backing. The adhesive coated material generally includes a copolymer, a solvent, a softener, and, if the softener is not therapeutically effective, a therapeutically effective amount of a drug. The adhesive coated material of Garbe is generally applied by conventional knife coating techniques then dried to remove the solvent. The Examiner noted that the detailed description of Garbe fails to teach a method of drying. However, applicants point out that all of the examples of Garbe suggest and teach oven drying techniques to remove the solvent from the applied coated material. Applicants specifically point out that the background section of the present invention addresses the problems associated with the utilization of conventional drying ovens with the coatings disclosed in the

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present invention (see page 1, through page 3, line 29). Oven drying practices have the undesirable tendency to remove volatile components from the coating along with the solvent. This undesirable result often requires over-formulation to compensate for the loss of volatile components in the oven drying process. Garbe fails to teach, suggest, or disclose the use of a heating surface and condensing surface as claimed in the present invention.

Huelsman discloses a method and apparatus for drying a substrate using a condensing surface located in close proximity to the surface of a substrate to be dried. A solvent is evaporated from a coating on the substrate and the vapor component of the solvent is then condensed on the condensing surface. Huelsman does not teach, suggest, or disclose the use of the method or apparatus for selectively removing a solvent from a coating containing both a solvent and volatile ingredient selected from drugs or liquid excipients.

Applicants aver that there is no basis for the combination of Garbe and Huelsman as applied by the Examiner. There must be some suggestion in the prior art to make the combination *In re Laskowski*, 10 USPQ 2d 1397, 1398 (Fed. Cir. 1989). For one thing, the references are devoid of any suggestion of the advantage of using a condensing surface to selectively removing a solvent from a coating composition containing volatile ingredients such as drugs or excipients as recited in claim 1. Further, neither reference teaches, suggests, or discloses the advantageous result of maintaining substantially all of the resident volatile components in the coated substrate, as recited in claim 2.

Thus applicants respectfully request withdrawal of the rejection of claims 1 and 2 for the foregoing reasons.

With respect to claims 3-4 and 6-21, applicants aver that the claims are further features or limitations upon the independent claim. Since the independent claim is patentable over the cited references for the reasons noted above, applicants assert that the additional limitations on the independent claim are also patentable. Withdrawal of the rejection of claims 3-4 and 6-21 is respectfully requested.

Conclusion

The prior art made of record and not relied upon is considered no more pertinent to the present invention than the references already of record.

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In view of the foregoing remarks, favorable reconsideration of the present application and the passing of this case to issue with all claims allowed is courteously solicited. Should the Examiner wish to discuss any aspect of this application, applicants' attorney suggests a telephone interview in order to expedite the prosecution of the application.

Respectfully submitted,

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Date

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